#### CONFIDENTIAL TISSUE COLLECTION AGREEMENT

This Tissue Collection Agreement (this "Agreement") is entered into this 15th day of November (the "Effective Date") by and between AmnioLife Corporation, a Delaware corporation with offices at 3542 NW 97th Blvd., Gainesville, FL 32606 ("AmnioLife") and TEXAS DONOR SERVICES whose registered office is at 2519 Westministe Peaplows. TX 77581 (referred to as Tissue Recovery Organization, hereinafter "TRO"). AmnioLife and the TRO are referred to individually as "Party" and collectively as "Parties."

#### RECITALS

WHEREAS, TRO is engaged in the consent, screening, collection, preservation, storage, shipping, and record-keeping of and for donated human tissues and,

WHEREAS, AmnioLife is experienced in the design, processing, distribution, and marketing of tissue allografts; and,

WHEREAS, TRO and AmnioLife in recognition of the need for and benefits that result from the availability of human tissue and tissue product allografts, desire to cooperate with each other in the provision of such products.

NOW. THEREFORE, in consideration of the mutual covenants and agreements contained herein, the Parties hereto agree as follows:

#### AGREEMENT

#### 1. Definitions.

Unless otherwise stated in this Agreement:

"Tissue" shall mean human cadaveric tissue collected by Life for AmnioLife Corp. that meet the Tissue Acceptance Criteria described in Exhibit A.

"Delivery" or "Delivery Time" shall mean the time that the Tissue is removed or delivered from the donor's body.

"Donor" shall mean a human Tissue donor that is the source of Tissue for transplantation, in accordance with agreed upon and established medical criteria and procedures and the Donor Acceptance Criteria described in Exhibit B.

"Collection" or "Recovery" shall mean the time or time interval, following Delivery, at or during which the Tissue was preserved by TRO.

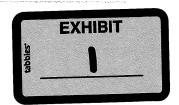
"Allograft" shall mean human Tissue products developed by AmnioLife consisting of any human tissue obtained by TRO to the specifications provided by AmnioLife.

#### 2. Term.

This Agreement shall commence on the Effective Date and shall remain in full force and effect for two (2) years from the date thereof (the "Initial Term"), unless terminated earlier in accordance with Section 4 below. Subject to such earlier termination, this Agreement shall automatically renew for additional one (1) year terms thereafter on the same terms and conditions unless either party hereto notifies the other party of its intention not to renew not later than ninety (90) days prior to the end of the initial term hereof and any such additional term.

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#### 3. Renewal.

Following the Initial Term, this Agreement shall automatically renew for successive one (1) year terms (each a "Renewal Term," and together with the Initial Term, the "Term") unless either Party has given notice, in writing, at least nine (9) months prior to the end of the then applicable Term of its desire to not renew this Agreement. For the sake of clarity, any and all Renewal Terms shall be subject to the terms and conditions of this Agreement.

#### 4. Termination.

This Agreement may be terminated prior to its expiration as follows:

At any time, by either Party upon written notice to the other Party, in the event (i) the other Party becomes insolvent or is unable to pay its obligations as they arise, or (ii) the other Party files any petition for bankruptcy or similar proceeding, or (iii) the other Party has a petition for bankruptcy or similar proceeding filed against it, and, in the cases described in subclauses (ii) and (iii) immediately above, such proceeding continues unstayed or without dismissal for sixty (60) days after the filing thereof;

At any time, by either Party, in the event a Force Majeure circumstance, as defined in Section 21 hereof, prevents the other Party from performing its obligations under this Agreement for a period of more than ninety (90) consecutive days:

Upon thirty (30) days written notice by either Party, in the event the other Party receives notification from an applicable governmental or regulatory body or court of competent jurisdiction, that it is not in compliance with any applicable federal, state, or local law or regulation and fails to cure such noncompliance, to the satisfaction of the applicable governmental or regulatory body or court, as the case may be, within thirty (30) days of such notification:

Upon thirty (30) days written notice by either Party, in the event the other Party breaches any representation, warranty, covenant or obligation under this Agreement and fails to cure such breach to the satisfaction of the other Party within thirty (30) days following receipt of written notice of such breach from the other Party:

By either Party immediately upon written notice to the other Party if such other Party (i) engages in any dishonesty that materially adversely affects the terminating Party; or (ii) such other Party knowingly, willfully or intentionally commits an act which could reasonably be expected to materially injure the reputation, business or business relationships of the terminating Party; or (iii) such other Party engages in any act of intentional misconduct or fraud in the course of its business.

#### 5. Effect of Expiration or Termination.

Upon the expiration or termination of this Agreement:

The Parties shall continue to perform their respective obligations hereunder until the effective date of such expiration or termination, as applicable. Upon notice of termination of this Agreement, TRO shall supply Tissues to AmnioLife, pursuant to this Agreement, if directed by AmnioLife and only if so directed by AmnioLife, then in accordance with pending orders submitted to TRO prior to the effective date of termination and AmnioLife shall pay the applicable fees in accordance with the terms and conditions of this Agreement.

The expiration or termination of this Agreement shall not act as a waiver of any right of either Party or release of any liability of either Party under this Agreement that may have accrued prior to the date of such termination or

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expiration.

Within fifteen (15) days after the effective date of expiration or any termination, each of the Parties shall return or destroy all copies of Confidential Information of the other Party; provided, however, that legal counsel may retain one copy of such Confidential Information for archival purposes only. In the event of such requested destruction, a Party shall provide to the other Party written certification of compliance therewith within three (3) days of such written request.

The following Sections (including any subsections thereunder) shall survive any expiration or termination of this Agreement: Section 5 and Sections 14-26.

#### 6. Compliance with NOTA.

The Parties hereby acknowledge that the National Organ Transplant Act (42 U.S.C., Section 274e) (as the same may have been, or may be, amended from time to time, the "Act"), prohibits the acquisition, receipt, and transfer of "Human Organs" (which may include, but is not limited to, non-cellular tissues such as amnion and placenta) for "valuable consideration." As used in the Act, the term "valuable consideration" does not include reasonable payments associated with, among other things, the transportation, processing, preservation, quality control, and storage of human organs or tissues. Each of the Parties acknowledges that the Fees provided for in Section 12 represent reasonable payments to TRO in accordance with the Act.

#### 7. Consent, Screening, Collection, and Donor Eligibility Determination.

TRO agrees that it shall be responsible for (i) obtaining legally valid informed consent for donation from all Donors, (ii) collecting, adequately completing, and documenting a donor risk assessment interview, (iii) obtaining and reviewing relevant medical records, and (iv) prior to release having its Medical Director, or lawfully authorized designee, assess Donor suitability based on a review and evaluation of TRO's records and the donor's relevant medical records or a summary of these generated by a properly trained individual, as further described in Exhibit C attached hereto. Donors of Tissue shall be screened in accordance with all applicable federal and State laws, rules and regulations (including, but not limited to, those of the State of Florida and FDA), and AATB standards and guidelines. All records required for suitability determination will be provided by TRO to AmnioLife within 5 business days of TRO completing its review and evaluation.

TRO shall collect Tissue for processing into allografts by AmnioLife according to the policies, procedures, and forms set forth in TRO's Standard Operating Procedures ("SOP") manual, which shall be incorporated herein by reference. Additional SOP forms may be added at any time by AmnioLife so long as AmnioLife provides a minimum thirty (30) days written notice of the need for additional forms or change to existing forms.

AmnioLife shall work with TRO in setting the specifications for Tissues to be collected, preserved, tested, and shipped that are intended for further processing by AmnioLife. The Parties' specifications shall be written and in compliance with all applicable state and federal laws, rules, and regulations. The Parties' initial specifications are set forth in Exhibit A attached hereto. The Parties may modify Exhibit A from time to time in accordance with the last sentence of Section 20 below.

TRO may, in its sole discretion, amend or modify its SOP manual and or individual policies related to Tissue collected under this agreement. To the extent any changes to the TRO SOP manual or policies affect the specifications outlined by AmnioLife under this agreement, TRO will give AmnioLife a minimum of thirty (30) days written notice prior to implementing the changes.

TRO shall provide AmnioLife with a statement of Donor Eligibility Determination that indicates (i) informed consent and (ii) the results of Donor screening and testing. A specimen copy of the Donor Eligibility Determination to be completed and provided is attached hereto as Exhibit C. This donor eligibility

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determination does not include, nor is TRO responsible for, technical or processing criteria related to release of products. AnnioLife agrees that it is responsible for documenting activities relating to processing, final product release, and a separate written processing release statement is required.

TRO will promptly inform AmnioLife of any change in information TRO obtains concerning Tissue or Donor suitability for use.

TRO agrees that its activities relating to Donor consent and Donor screening, culturing, and collection of Tissue have been reviewed and approved by TRO's Medical Director and/or Quality Department, and that such activities comply in all respects, and will continue to comply in all respects at all times during the Term of this Agreement, with all applicable Federal and State laws, rules and regulations, and accreditation standards, including but not limited to, those promulgated by the American Association of Tissue Banks ("AATB") and human tissue requirements of the U.S. Food and Drug Administration ("FDA"), including, without limitation, the FDA's current Good Tissue Practice.

#### 8. Preservation, Packaging, Shipping, and Delivery.

TRO shall preserve Tissue in compliance with all applicable federal and State laws, rules and regulations (including, but not limited to, those promulgated by the FDA), and AATB standards and guidelines, and according to specifications outlined in the Tissue Acceptance Criteria (Exhibit A). AmnioLife will provide all storage/shipping containers and either supply recovery kits or utilize kits from TRO and reimburse them for use of the kits for donors intended for AmnioLife. AmnioLife shall provide to the TRO its preferred preservation solution(s) that AmnioLife in its reasonable judgment, deems suitable for maintaining Tissue suitable for use during the time it is stored and shipped. Tissues will be shipped on AmnioLife's FedEx, or designated carrier, account.

TRO shall package, label and ship Tissue in compliance with all applicable federal and State laws, rules and regulations (including, but not limited to, those promulgated by the FDA), and AATB standards and guidelines, and according to specifications outlined in the Tissue Acceptance Criteria (Exhibit A). TRO shall provide shipping containers (e.g. Styrofoam and cardboard box/outer package) that are validated to be suitable for maintaining Tissue suitability for use during shipment.

AmnioLife shall be responsible for FedEx shipping expenses associated with the shipment of Tissues from TRO to AmnioLife. Risk of loss and title to Tissue shipments shall pass to AmnioLife upon delivery to AmnioLife's designated carrier.

Tissue may be shipped prior to completing all steps of the Donor suitability assessment. All Tissue shipped by TRO will be labeled:

"QUARANTINE - ELIGIBILITY PENDING - DONATED HUMAN TISSUE"

#### 9. Supply of Tissue

AmnioLife shall order and TRO shall collect and supply to AmnioLife Tissue in accordance with the terms and conditions set forth in this Agreement.

AmnioLife agrees to accept Tissue from TRO that has been ordered by AmnioLife, and collected, packaged, labeled and shipped by TRO in compliance with the terms and conditions of this Agreement, including, but not limited to, the applicable criteria set forth in Tissue Acceptance Criteria (Exhibit A) and Donor Acceptance Criteria (Exhibit B).

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#### 10. TRO Collection Sites

TRO collects Tissue from healthcare facilities (collection sites) that have signed TRO's recovery/collection Agreement. AmnioLife agrees to keep confidential the identity of these collection sites that it will become aware of during the normal course of donor and tissue record review and evaluation. AmnioLife also agrees that the TRO-collection site relationship is exclusively TRO's and will at no time attempt to interfere, compete, or interrupt TRO's relationship with its original collection-site facilities named in Schedule A and being used by TRO only at the time this Agreement was executed. AmnioLife agrees that it will not provide TRO collection-site information to any other company who may be an actual or potential TRO competitor. This clause in no shape or form restricts AmnioLife from partnering with additional collection facilities in the USA.

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#### 11. Screening

TRO shall make its best effort to identify and adequately screen eligible donors and provide Tissue to AmnioLife that conforms to the terms and condition of this Agreement. Occasionally, and regardless of the diligence used to screen and test donors, Tissue will not conform. For example: third-party laboratories may report reactive or positive test results, or surgical trauma may preclude clinical use of the Tissue. In such an event, AmnioLife may utilize the Tissue for non-clinical use or discard the Tissue. In either case, AmnioLife shall be responsible for documenting the affected Tissue's final disposition. Therefore, if Tissue received by AmnioLife does not conform to the terms and conditions of this Agreement because of results received from third-party testing facilities or from surgical trauma, the Parties agree to share the costs of the non-conformance by AmnioLife reimbursing TRO as indicated in Exhibit E (Reimbursement Fee Schedule). Thereafter, TRO shall replace the non-conforming Tissue and AmnioLife shall reimburse TRO for the conforming replacement as indicated in Exhibit E.

#### 12. Fees and Payments.

AmnioLife shall reimburse TRO for Tissues ordered by AmnioLife as indicated in Exhibit E (Reimbursement Fee Schedule). The reimbursement fee is limited to costs associated with regulatory compliance and acquiring, handling, and providing such Tissues; there is no charge associated with the Tissue itself, which is donated. The Reimbursement Fee is due and payable to TRO within thirty (30) days following receipt of invoice. AmnioLife may withhold payment of any amounts that it has notified TRO in writing are in dispute, pending resolution by both Parties. Any amounts past due (other than amounts subject to a bona fide dispute) shall accrue interest at a rate of the lesser of one and one half percent (1.5%) per month or the maximum rate allowed by law. Electronic submission of invoices will need to be sent to apdept@amniolife.com.

TRO shall invoice AmnioLife in accordance with the fee schedule attached hereto as Exhibit E. AmnioLife shall pay TRO within thirty (30) days of AmnioLife's receipt of invoices for acceptable Tissue.

AmnioLife will accept and pay a "micro/sero pass fee" which is equal to a reject fee after the micro and sero results to be reported to AmnioLife by the lab. TRO will invoice this fee within 8 days of tissue shipment to AmnioLife.

#### 13. Quality Assurance.

AmnioLife shall have the right to audit TRO's facilities and interview its staff for the purpose of quality assurance. Any such audits shall be conducted after the Parties agree to the audit's date, time, and scope of activities that will be subject to auditing. Audits will occur following a minimum thirty (30) day notice unless an audit is required to satisfy AATB, State or FDA requirements from AmnioLife, occur during normal business hours, and not disrupt on-going operations. Audit results will remain confidential in accordance with the terms set forth in Section 17 below.

AmnioLife's audit staff shall conduct themselves in an appropriate manner and will not unnecessarily interfere with TRO's normal business operations.

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Each Party shall inform the other of any complaints and/or suspected adverse reactions or outcomes related to the Tissue supplied by TRO within 48 hours of becoming aware of such actual or suspected event.

#### 14. Mutual Representations and Warranties; Disclaimer of Certain Warranties.

Each Party represents and warrants to the other Party as of the Effective Date as follows: (a) such Party is a corporation or other entity duly incorporated or organized (as the case may be), validly existing and in good standing under the laws of the state in which it is incorporated or organized and has full power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as is contemplated to be conducted by this Agreement; (b) such Party has the legal power, authority and right to enter into this Agreement and to perform its respective obligations set forth herein; (c) this Agreement has been duly executed by the duly authorized representative of such party and constitutes the valid and binding obligation of such party, enforceable against such party in accordance with its terms, except as such enforceability may be limited by (1) bankruptcy, insolvency, reorganization, moratorium or other similar laws, now or hereafter in effect, relating to or limiting creditors' rights generally, and (2) general principles of equity (whether considered in an action in equity or at law); and (d) the execution, delivery and performance of this Agreement by such Party do not and will not; (1) conflict with, or constitute a default under, any agreement, instrument or understanding, oral or written, to which it is a party or by which it is bound, nor (2) to such Party's knowledge, violate any laws, rules or regulations of any governmental authority having competent jurisdiction over it.

Except as otherwise set forth in this Agreement, Tissue is delivered by TRO with no warranty as to the merchantability or fitness for a particular purpose.

Tissue from living donors has been collected and provided by TRO following donor informed consent, and screened by a trained individual using a donor risk assessment questionnaire, results of a history and physical examination, and review of relevant medical records. Infectious disease testing of donor blood specimens is performed on an appropriate donor specimen collected within seven days prior to or after tissue collection. Testing used for donor suitability is performed by a laboratory registered with FDA, which is either certified to perform such testing on human specimens in accordance with Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) and 42 CFR Part 493, or has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services.

#### 15. Insurance.

Both Parties shall maintain a separate product liability policy or policies of insurance in the amount of no less than \$1 million per occurrence and no less than \$3 million in the aggregate for insuring against liability which may be imposed arising out of acts or omissions to include (1) comprehensive general liability providing coverage for personal injury, bodily injury, property damage; and (2) professional liability. These insurance certificates are available at request by either Party.

#### 16. Recall.

In the event of a recall, field correction, market withdrawal, stock recovery, or other similar action with respect to any Tissue (a "Recall"), the Parties shall work together to safely and effectively conduct such Recall as quickly and efficiently as possible. AmnioLife shall promptly reimburse TRO for all reasonable out-of-pocket expenses incurred by TRO in connection with any such Recall attributable to any negligent act or omission by or on behalf of AmnioLife that necessitated or warranted the Recall. TRO shall promptly reimburse AmnioLife for all reasonable out-of-pocket expenses incurred by AmnioLife in connection with any such Recall attributable to any negligent act or omission by or on behalf of TRO that necessitated or warranted the Recall.

#### 17. Confidentiality.

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While this Agreement is in effect, and for a period of two (2) years after the termination of the Agreement, neither AmnioLife, nor TRO, nor their respective affiliates, directors, shareholders, officers, employees, agents, or assigns (collectively, the "Affiliates") shall divulge to any person or entity the nature of this Agreement, who the Agreement is with, the Parties' names, or any Confidential Information (as hereinafter defined), except: (i) as required in the course of performing the obligations hereunder, (ii) to attorneys, accountants, and other advisors, (iii) with the express written consent of AnnioLife or TRO, or (iv) as required by law. The term "Confidential Information" shall mean any information relating to AmnioLife or TRO or their respective business which is, (1) disclosed to the other (or to the other's Affiliates) during the negotiation of and performance of this Agreement and (2) is marked "Confidential" if provided in writing, or if delivered verbally, is reduced to writing within thirty (30) days and marked "Confidential." "Confidential Information" shall not include any information, which (i) becomes public knowledge without breach by the other of this Agreement; (ii) is obtained by the other (or the other's Affiliates) from a person or business entity under circumstances lawfully permitting its disclosure to others: (iii) may be demonstrated to have been known at the time of receipt thereof as evidenced by tangible records; or (iv) is required to be disclosed as a result of a judicial order or decree or governmental law or regulation. If a Party makes a disclosure of Confidential Information which is permitted by the terms of this Agreement, such Party shall be responsible, to the greatest extent legally permissible, for ensuring that the person to whom it is disclosed maintains the confidentiality of such Confidential Information in accordance with the terms of this Agreement.

The parties acknowledge that the breach by a Party of any provision of this Section 17 may cause irreparable harm and significant injury to the other Party, the extent of which may be difficult to ascertain and for which there may be no adequate remedy at law. Accordingly, in addition to any other remedy available under this Agreement or at law, the Parties agree that the non-breaching Party shall have the right to seek temporary, preliminary and permanent injunctive relief, without the necessity of proving actual damages or posting a bond, to prevent any such breach or a threat thereof.

#### 18. Independent Contractor.

TRO is an independent contractor and nothing in this Agreement creates the relationship of partnership, joint venture, sales agency, or principal and agent, and neither Party is the agent of the other, and neither Party may hold itself out as such to any other Party, and TRO has no power or authority in any way to bind AmnioLife contractually. TRO shall be free to manage and control its business as it sees fit without the management, control, or assistance of AmnioLife, except as otherwise prescribed herein.

#### 19. Governing Law and Choice of Forum.

This Agreement shall be governed by and construed in accordance with the laws of the State of Florida, County of Alachua, without regard to its choice of law provisions.

#### 20. Entire Agreement; Amendments.

This Agreement (including, for the sake of clarity, the preamble and Recitals on page 1 of this Agreement, which are incorporated by reference herein) and all Exhibits and attachments (which are incorporated by reference in this Agreement) contain the entire understanding of the Parties with respect to the matters contained herein and merges and supersedes all prior and contemporaneous agreements and understandings between the parties, whether oral or written, with respect to the subject matter of this Agreement. In case one or more amendments, modifications, or alterations of this Agreement become necessary, the Parties shall negotiate in good faith on such amendments, modifications, or alterations. This Agreement may be amended, modified, or altered only by an instrument in writing duly executed by both Parties. For the sake of clarity, any references to "this Agreement" shall be deemed to include all Exhibits attached hereto, which are made a part hereof.

#### 21. Force Majeure.

The Parties hereto shall not be liable in any manner for the failure or delay of fulfillment of all or part of this Agreement, directly or indirectly, owing to governmental orders or restrictions, war, war-like conditions, revolution, riot, looting, strike, lockout, fire, flood or other external causes or circumstances beyond the Parties' reasonable control. Neither TRO nor AmnioLife shall be liable for any default, damages (direct, indirect, foreseeable, unforeseeable, consequential, or punitive), or delays in shipment for any cause beyond its reasonable control.

#### 22. Assignability.

Neither Party to this Agreement may assign any rights or obligations under this Agreement to any other entity (unless the majority interest in the entity is owned by the Party assigning its rights or obligations) or person without the advance written consent of the other Party; provided, however, if TRO is acquired (whether by asset sale, merger, consolidation or equity sale), it is agreed that this TISSUE COLLECTION AGREEMENT between AmnioLife and TRO will continue and that the new ownership of TRO will continue to provide Tissue at the current levels ordered in the month prior to the change of ownership for the remainder of the Term; provided further, however, that if AmnioLife is acquired (whether by asset sale, merger, consolidation, equity sale or otherwise), it is agreed that AmnioLife may assign this TISSUE COLLECTION AGREEMENT between AmnioLife and TRO to the buyer or resulting corporation without TRO's prior written consent.

#### 23. Severability.

If any one or more of the provisions of this Agreement shall for any reason be held to be illegal or unenforceable, such invalidity or unenforceability shall not affect any other provision of this Agreement or the validity or enforceability of such provision. The unenforceable provision shall be treated as severable and the remaining provisions shall nevertheless continue in full force and effect, giving maximum effect to the intent of the Parties in entering this Agreement.

#### 24. Counterparts.

This Agreement may be executed in one or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. Counterparts submitted by fax or electronically shall have the same force and effect as the original.

#### 25. Indemnification.

- (1) TRO shall indemnify, defend and hold AmnioLife, its officers, directors, employees, agents, and Affiliates harmless from and against actual losses, damages, liabilities, costs and expenses, including, without limitation, reasonable attorneys' fees and court costs, that may result from any demand, claim or litigation to the extent relating to, resulting from, or arising out of (a) any negligent act or omission or willful misconduct of TRO or its employees, agents, contractors or Affiliates; or (b) any breach by TRO of this Agreement or any warranty, representation or covenant contained herein, or (c) any violation of applicable laws by TRO or its employees, agents, contractors or Affiliates.
- (2) AmnioLife shall indemnify, defend and hold TRO, its officers, directors, employees, agents, and Affiliates harmless from and against actual losses, damages, liabilities, costs and expenses, including, without limitation, reasonable attorneys' fees and court costs, that may result from any demand, claim or litigation to the extent relating to, resulting from, or arising out of (a) any negligent act or omission or willful misconduct of AmnioLife or its employees, agents, contractors or Affiliates; or (b) any breach by AmnioLife of this Agreement or any warranty, representation or covenant contained herein, or (c) any violation of applicable laws by AmnioLife or its employees, agents, contractors or Affiliates.

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The provisions of Section 25 apply only to matters brought by other entities, which are not a party to this Agreement. The provisions of Section 25 shall not apply to prior or subsequent agreements that have been or may be entered into between TRO and AmnioLife.

Except with respect to a Party's indemnification obligations set forth in this Section 25, in no event shall either Party be liable for any lost profits or revenue or indirect, special, incidental, consequential or punitive damages, losses or expenses, even if such Party has been advised of the possibility of such loss or damage.

#### 26. Notices.

Any notice or report required or permitted to be given or made under this Agreement by one of the Parties to the other Party shall be in writing and shall be deemed to have been sufficiently given for all purposes, and effective as of the date of receipt, if mailed by certified mail return receipt requested, postage prepaid, addressed to such other Party at its respective address as follows:

If to TRO:

TEXAS DONOR SERVICES 2514 Westminister PEARLAND TY 22581 If to AmnioLife:

AmnioLife Corporation Gene S. Elliott 3542 NW 97<sup>th</sup> Blvd. Gainesville, FL 32653

#### 27. Headings.

The various section headings are inserted for convenience of reference only and shall not affect the meaning or interpretation of this Agreement or any section thereof.

[Signature Page Follows]

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IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorized

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representatives as of the date first above written.				
	AmnioLife Corporation			
By: Apple Little	By:			
Name: Tose Quintana	Name: Gene S Elliott			
Title: President	Title: Chief Operating Officer			
Date: 11-15-2015	Date: 11-15-2015			

#### Exhibit A

#### 1. Tissue Acceptance Criteria

1. AmnioLife Donor Acceptance Criteria Attached

#### H. Tissue Preservation

- 1. TRO shall preserve Tissue in compliance with all applicable federal and State laws, rules and regulations (including, but not limited to, those promulgated by the FDA), and AATB standards and guidelines, and according to specifications provided by AmnioLife.
- AmnioLife shall provide validated shipping containers for maintaining Tissue viability during the time it is in transit.
- 3. AmnioLife Corp. shall provide at its expense to TRO a known shipper number for shipping donor tissue to our facility.
- 4. Tissue will either be shipped on wet or dry ice.

#### III. Tissue Packaging and Shipping

1. TRO shall package and ship Tissue in compliance with all applicable federal and State laws, rules and regulations (including, but not limited to, those promulgated by the FDA), and AATB standards and guidelines, and according to specifications provided jointly by TRO and AmnioLife.

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Exhibit B

Donor Acceptance Criteria

1. See Attached Criteria

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#### Exhibit E

#### Reimbursement Fee Schedule

Donors - Collected disarticulated in individual units or Leg enbloc recovery. Shipped on Wet or Dry Ice.

#### Described as the following

- Bilateral Femurs
- Bilateral Tibia's (with whole patella attached)
- · Bilateral Fibula's
- · Bilateral Humerus
- Bilateral Radius
- · Bilateral Ulna
- Hemi Pelvis / Iliac Crest
- 2-Anterior Tibialis Tendons
- 2-Posterior Tibialis Tendon
- 2 Achilles Tendons
- 2- Peroneus Longus
- 2-Gracilis Tendons
- 2-Semitendinosus Tendons
- 2-Fascia Lata

\*\*\*\*\*\*(NOTE: Humerus, Radius and Ulna - if NOT included in "whole donor" will not be a reduction in reimbursement if not included)

- 1. Male Donors
  - 18-55 \$11,500
  - 56-70 \$8,000
  - 71-85 \$7,500
- 2. Female Donors
  - 18-45 \$8,500
  - 46-65 \$4,500
- Skin Free-Hand Full Thickness Cut (\*AmnioLife working on protocols for this and cannot accept skin at this time)
  - \$4,000
- 4. If recovery organization provides recovery pack, Fee will be charged to AmnioLife as a different line item of 500.00 per pack. (Pack manifest will be delivered to you for review) If AmnioLife provides recovery pack, there will be no additional reimbursement to for packs.

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### 5. Reject Fee - \$3,500.00

- Positive Serology
- Perfinent data found in medical background making to donor unsuitable for transplant
- Autopsy report findings
- ALS issues (additional I's and O')
- This would include no additional charge for any recovery pack used

### 6. Micro/Scro

- Blood tubes will be provided
- · Micro swabs will be provided
- Any shipping components will be provided
- Our Overnight shipping company account number will be provided

### **Tissue Supply Agreement**

This Tissue Supply Agreement (this "Agreement") is made and entered into as of this It's day of 2017 (the "Effective Date"), by and between AmnioLife Corporation, a Florida corporation ("AMNIOLIFE") with a principal office at 3542 NW 97<sup>th</sup> Boulevard, Gainesville, FL 32606, and Texas Donor Services ("TDS"), an Texas company that resides at 1607 N. Main St #8, Penhand to 77581 . AMNIOLIFE and TDS may also be referred to as a Party or together the Parties.

WHEREAS, TDS facilitates the recovery of human tissues suitable for transplantation or research; and

WHEREAS, TDS and AMNIOLIFE desire to enter into an agreement pursuant to which TDS will transfer custody of recovered human tissues to AMNIOLIFE in order that AMNIOLIFE may utilize same to meet its human tissue allograft needs; and

WHEREAS, TDS and AMNIOLIFE, in recognition of the need for, and benefits that result from, the availability of tissues for transplantation, desire to cooperate in the provision of certain tissues for recovery and processing in accordance with the terms set forth in this Agreement.

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein, the parties agree as follows:

#### **DEFINITIONS** 1.

### The following definitions shall apply throughout this Agreement:

- 1.1. "Applicable Laws and Standards" shall mean, collectively, (a) all applicable current and future federal, state, and local laws, rules and regulations in effect in the United States now or at any time hereafter during the term of this Agreement including, but not limited to, the U.S. Food and Drug Administration 21CFR 1270 and 21CFR1271, and the National Organ Transplant Act (42 U.S.C., Section 274e) ("NOTA"); (b) all applicable current and future federal, state, and local laws, rules and regulations in effect in any country in which TDS performs the recovery of human tissue at any time during the term of this Agreement; and (c) all applicable current and future standards, rules and requirements of the American Association of Tissue Banks ("AATB").
- 1.2. "Donor Acceptance Guidelines" shall mean, collectively, (i) the donor suitability criteria of the AATB, (ii) the donor acceptance and other suitability criteria of AMNIOLIFE, from time to time in effect, and included in this Agreement as Schedules A & B, and (iii) the donor eligibility criteria of the FDA or any other applicable local, state or federal governmental entity, from time to time in effect. Notwithstanding the foregoing, or any other provision set forth herein, the ultimate determination of whether any Donor Tissue is suitable for processing and release for transplantation shall be in the sole and absolute discretion of AMNIOLIFE.

- 1.3. "Donor Record File" shall mean the Donor Record File which is collected/completed by TDS in connection with the recovery of all Donor Tissues and which is forwarded by TDS to AMNIOLIFE, together with Donor Tissue and/or within five (5) business days upon discovery of new or revised information. Donor Record File includes all available and relevant medical and donor records that are released to TDS, including without limitation, a copy of hospital/emergency services admission and treatment records, Donor's medical, social and behavioral risk assessment, Donor consent and/or authorization for donation, Donor plasma dilution evaluation, documentation of all bacteriological cultures and serological testing results, if applicable and released to TDS, documentation of aseptically recovered tissue and emergency medical service (EMS) records. TDS shall use donor information forms, pre-approved by AMNIOLIFE, to document the services it performs under this Agreement. The Parties agree it will provide the other Party to this Agreement with a minimum of thirty (30) days notice prior to implementing changes to approved documentation or changing operating practices related to services provided under this Agreement unless such changes are mandated by any change in an applicable law, regulation, guideline, or other administrative directive not originating with either of the Parties. The initial pre-approved donor information forms are attached to this Agreement as Schedule D and incorporated fully herein by reference. Autopsy reports are not a component of the Donor Record File but TDS will use commercially reasonable efforts to obtain autopsy reports and agrees to provide a copy of an autopsy report to AMNIOLIFE within two (2) business days after TDS obtains an autopsy report. TDS will use commercially reasonable efforts to provide AMNIOLIFE a donor's recent hospital records and EMS runsheet(s) for donor deaths within a reasonable time after donor date of death. If an autopsy is not performed on a donor, TDS will only attempt to provide a donor death certificate to AMNIOLIFE if TDS is unable to obtain release to TDS of a donor's hospital medical record. AMNIOLIFE acknowledges that the clarity, composition, legibility, comprehensiveness and accuracy of any of the foregoing records are outside of TDS's control and will not be cause for delay of payment by AMNIOLIFE to TDS.
- 1.4. "Donor Tissue" shall mean any human tissue screened and approved by **AMNIOLIFE** and recovered by **TDS** and sent to **AMNIOLIFE** under this Agreement. Final suitability approval of tissue provided by **TDS** to **AMNIOLIFE** would be determined by **AMNIOLIFE** upon provision and review of all available donor information in Section 1.3 above.
- 1.5. "Donor Recovery Fees" shall mean the reimbursement that is due **TDS** for the recovery expenses and service fees incurred during the normal course of a human tissue recovery for **AMNIOLIFE**.

### 2. TISSUE RECOVERY SERVICES

**AMNIOLIFE Responsibilities**. Pursuant to the terms and conditions hereof, **AMNIOLIFE** will:

- 2.1. Bear the risk and expense of shipping Donor Tissue from TDS to AMNIOLIFE
- 2.2. Supply qualified shipping containers in accordance with the terms and conditions hereof in the event **TDS** chooses to utilize own tissue shipping container **TDS** will provide **AMNIOLIFE** with the qualification certificate for the shipping container.
- 2.3. Direct the processing of Donor Tissue into any allograft products **AMNIOLIFE** elects, in **AMNIOLIFE**'s sole discretion, so long as the restrictions, if any, on the donation consent/authorization document are followed, and **AMNIOLIFE** may distribute such processed Donor Tissue in any lawful manner, which **AMNIOLIFE** elects, in **AMNIOLIFE**'s sole discretion.
- 2.4. Exercise sole and absolute discretion to determine whether such Donor Tissue is suitable for processing and release in accordance with the Donor Acceptance Guidelines and all other Applicable Laws and Standards.
- 2.5. Have a Medical Director that is responsible for final say on donor suitability for transplant.

# TDS Responsibilities. Pursuant to the terms and conditions hereof, TDS will:

- 2.6. Provide recovered Donor Tissue from tissue donors that meet AMNIOLIFE's Donor Acceptance Guidelines, complete donor history screening, and report to AMNIOLIFE all information applicable to such Donor Tissue that TDS is aware of at the time of Donor Tissue recovery, or of which TDS becomes aware at any time thereafter. TDS shall use its reasonable best efforts to ensure that its work performed under this Agreement is accomplished in accordance with all Applicable Laws and Standards and that all such Consents and/or Authorizations shall permit the Donor Tissue to be used by AMNIOLIFE under the terms and conditions of this Agreement.
- 2.7. Package, when applicable, cultures, blood and or serum samples along with all other required testing specimens for shipment to **AMNIOLIFE** or a contract test laboratory. Shipping will be at **AMNIOLIFE**'s risk and expense utilizing a reputable courier selected by **AMNIOLIFE**. **TDS** shall inform **AMNIOLIFE** of the logistics associated with any shipments to **AMNIOLIFE** to help ensure safe and timely receipt.
- 2.8. Fulfill all applicable reporting, tracking and other requirements of regulatory agencies, self-regulatory organizations or governmental entities that have jurisdiction with respect to **TDS** and the recovery services provided by **TDS** hereunder or the Donor Tissue;

- 2.9. Be responsible for obtaining legally valid consents and/or authorization from all donors of Donor Tissue;
- 2.10. Have a Medical Director.

### 3. DONOR RECOVERY FEES

- 3.1. <u>Fees.</u> AMNIOLIFE will reimburse TDS for its services ("Donor Recovery <u>Fees</u>") in connection with TDS recovery of Donor Tissues shipped to **AMNIOLIFE**. The Donor Recovery Fees are detailed in **Schedule** C of this Agreement which schedule is attached hereto and fully incorporated herein by reference. These fees represent reasonable payments to TDS in accordance with NOTA and/or any other applicable regulations and guidelines.
- 3.2. Payment Terms. TDS will transmit electronically (email or fax) to AMNIOLIFE a copy of the Donor Record File for review and acceptance by AMNIOLIFE. Upon acceptance by AMNIOLIFE of Donor Tissue based on Donor Record File transmitted to AMNIOLIFE, TDS will transmit an invoice to AMNIOLIFE for payment of Donor Recovery Fees by AMNIOLIFE under net 30 terms for payment to TDS.

Upon receipt of payment from AMNIOLIFE, title to Donor Tissue passes to AMNIOLIFE and TDS will send the Donor Tissue to AMNIOLIFE. AMNIOLIFE will not reimburse TDS for any Donor Tissue that does not conform to the Donor Record File. AMNIOLIFE will have twenty-four (24) hours from time of receipt of shipment by AMNIOLIFE to reconcile the Donor Tissue to the Donor Record File and to notify TDS of any nonconformity. If any Donor Tissue transmitted to, and paid for by, AMNIOLIFE do not conform to the Donor Record File or to guidelines in Schedule A, as confirmed by TDS's review of AMNIOLIFE communication of nonconformity information, TDS will issue a return authorization number to AMNIOLIFE for AMNIOLIFE to return the nonconforming Tissue to TDS. TDS will credit AMNIOLIFE the amount paid by AMNIOLIFE for nonconforming Donor Tissue that was approved and ordered by AMNIOLIFE based on AMNIOLIFE's review of the Donor Record File. In the event of conflict between Schedule A and C, Schedule C shall control. If AMNIOLIFE does not make any required payment to TDS, when due, TDS, in its sole discretion, may immediately suspend the performance of any services under this Agreement without waiving its rights under Section 5.2 of this If TDS suspends performance under this Agreement due to AMNIOLIFE payment default, TDS will use reasonable efforts provide notice to AMNIOLIFE by telephone, email or in person communication in connection with or promptly following the suspension of performance. Interest shall accrue on any payment amount in default at the rate of one and one half percent (1.5%) per month or the maximum lawful rate, whichever is less, until the amount in default is received by TDS.

3.3. Compliance with NOTA. TDS and AMNIOLIFE acknowledge that the National Organ Transplant Act (42 U.S.C., Section 274e, the "Act") prohibits the

acquisition, receipt and transfer of "Human Organs" (which includes bone and tissue) for "valuable consideration." As used in the Act, the term "valuable consideration" does not include reasonable payments associated with, among other things, the transportation, processing, preservation, quality control and storage of Human Organs. Each of the parties acknowledges that the fees provided for in this Agreement represent reasonable payments in accordance with the Act. The reimbursement fees provided for in this Agreement represent reasonable payments to **TDS** in accordance with the Act This reimbursement fee is based in the actual cost of donor tissue recovery, donor testing, donor screening, donor storage, donor shipping and the indirect cost **TDS** facilities including: personnel, educational efforts, referral screening processes and administrative costs associated with managing the **TDS** operation.

### 4. INSURANCE

4.1 <u>Insurance</u>. Both parties shall maintain a separate policy or policies of insurance in the amount of one (\$1) million dollars per occurrence and two (\$2) million dollars in the aggregate for insuring against liability which may be imposed arising out of acts or omissions to include: 1) comprehensive general liability providing coverage for personal injury, bodily injury, property damage; and 2) professional liability. Both Parties agree to name the other Party as an additional insured and provide evidence of such upon request by the other Party.

### 5. TERM AND TERMINATION

- 5.1.<u>Term.</u> This Agreement shall become effective as of the Effective Date and shall remain in effect for a period of three (3) year thereafter ("<u>Initial Term</u>"). This Agreement shall be subject to automatic, successive renewal terms of three years, unless either of the parties provides the other with written notice of its intent to terminate at least ninety (90) days prior to the expiration of the Initial Term or the then current renewal term, whichever is applicable, unless otherwise terminated as provided in Section 5.2.
- 5.2. This Agreement may be terminated by either Party as follows:
  - 5.2.1. Due to a material breach by the other Party of any of its obligations herein, upon thirty (30) calendar days written notice to the breaching Party which notice shall identify the alleged breach with sufficient specificity, but only if the breaching Party fails to remedy said breach within thirty (30) calendar days of such written notice; or
  - 5.2.2. Immediately upon the insolvency or filing for bankruptcy, or notice of either, by the other Party.
- 5.3. Upon termination of this Agreement, **AMNIOLIFE** shall be liable to **TDS** for amounts specifically owed to **TDS** pursuant to Section 3.1 for recovery services rendered prior to the effective date of the termination of this Agreement.

#### 6. Indemnification and Warranties

### 6.1. Indemnification.

- 6.1.1. TDS shall indemnify, defend and hold AMNIOLIFE, its officers, directors, employees, agents and affiliates ("AMNIOLIFE Indemnified Parties"), harmless from and against any and all losses, claims, damages, liabilities, costs and expenses, including without limitation, reasonable attorneys' fees, court costs and legal fees, that may result from any demand, claim or litigation relating to, resulting from or arising out of (i) any act or omission of TDS that breaches its obligations under this Agreement or any warranty, representation or covenant of TDS contained herein, provided however, that TDS shall have no obligation to indemnify any AMNIOLIFE Indemnified Parties pursuant to this section 6.1.1. to the extent that such losses are found by a trier of fact to be primarily caused by the negligence, gross negligence or intentional misconduct on the part of any AMNIOLIFE Indemnified Party.
- 6.1.2. **AMNIOLIFE** shall indemnify, defend and hold **TDS**, its officers, directors, employees, agents and affiliates ("**TDS** Indemnified Parties"), harmless from and against any and all losses, claims, damages, liabilities, costs and expenses, including without limitation, reasonable attorneys' fees, court costs and legal fees, that may result from any demand, claim or litigation relating to, resulting from or arising out of (i) any act or omission of AMNIOLIFE that breaches its obligations under this Agreement or any warranty, representation or covenant contained herein, provided however, that **AMNIOLIFE** shall have no obligation to indemnify any **TDS** Indemnified Parties pursuant to this section 6.1.2 to the extent that such losses are found by a trier of fact to be primarily caused by the negligence, gross negligence or intentional misconduct on the part of any **TDS** Indemnified Party.
- 6.2. <u>Survival of Obligations</u>. The respective obligations of the parties hereto pursuant to this Section 6 shall survive the termination of this Agreement.
- 7. Representations, Warranties and Covenants of TDS. TDS represents, warrants and covenants to AMNIOLIFE as follows:
  - 7.1. All Donor Tissues supplied to **AMNIOLIFE** have been procured by **TDS** in compliance with all Applicable Laws and Standards and in accordance with **AMNIOLIFE**'s written criteria or AMNIOLIFE approved equivalent **TDS** standard operating procedures (SOPs) as outlined in **Schedules A & B** attached hereto and fully incorporated herein by reference;
  - 7.2. All facilities used by **TDS** are operated in compliance with Applicable Laws and Standards;
  - 7.3. **TDS** currently conducts, and will at all times during the terms of this Agreement, continue to conduct its business in a manner consistent with the standards of industry business practices;

- 7.4. **TDS** is fully authorized to enter into and perform its obligations outlined in this Agreement and that its execution and performance of this Agreement will not (i) conflict with, or result in a breach or default under, any agreement, contract, arrangement, mortgage or indenture to which it is bound, (ii) result in the creation of any lien, encumbrance or pledge upon any of the properties or assets of **TDS**, or (iii) violate statutes, rules, regulations or orders applicable to **TDS**;
- 7.5. The rights granted under this Agreement do not violate any rights previously granted by **TDS** to any third party.
- 8. Representations, Warranties and Covenants of AMNIOLIFE. AMNIOLIFE represents, warrants and covenants to TDS as follows:
  - 8.1. All Donor Tissues provided to **AMNIOLIFE** hereunder shall be processed and otherwise handled by **AMNIOLIFE** in compliance with all Applicable Laws and Standards and in accordance with **AMNIOLIFE**'s written policies and procedures;
  - 8.2. **AMNIOLIFE** currently conducts, and will at all times during the terms of this Agreement, continue to conduct its business in a manner consistent with the standards of industry business practices;
  - 8.3. All facilities used by **AMNIOLIFE** are operated in compliance with all Applicable Laws and Standards;
  - 8.4. **AMNIOLIFE** is fully authorized to enter into and perform its obligations outlined in this Agreement and that its execution and performance of this Agreement will not (i) conflict with, or result in a breach or default under, any agreement, contract, arrangement, mortgage or indenture to which it is bound, (ii) result in the creation of any lien, encumbrance or pledge upon any of the properties or assets of **AMNIOLIFE**, or (iii) violate statutes, rules, regulations or orders applicable to **AMNIOLIFE**;
  - 8.5. The rights granted under this Agreement do not violate any rights previously granted by **AMNIOLIFE** to any third party.

# 9. Governing Law and Compliance with All Applicable Law

- 9.1. Governing Law. This Agreement shall be governed by the laws of the State of Florida, County of Alachua excepting its conflicts of law principles. Any action or proceeding arising under or relating to this Agreement shall be brought in the courts of the State of Florida, County of Alachua and each of the parties consents to the jurisdiction of such courts.
- 9.2. Compliance with all Applicable Law. Each Party shall comply in all respects with all Applicable Laws and Standards in connection with its performance under this Agreement.

9.3. Accreditation. TDS and AMNIOLIFE shall have sole responsibility for its own on-going compliance with regard to accreditation requirements under the AATB, FDA federal regulations, and any other applicable industry, governmental or regulatory standards, guidelines or requirements concerning the subject matter contemplated herein. Each Party agrees to promptly notify the other Party in writing in the event that an accrediting or regulatory agency determines that it is non-compliant. Each Party shall cooperate in any way the other Party may reasonably request with regard to any such ongoing compliance or accreditation requirements.

#### 10. Miscellaneous

10.1. Confidentiality. While this Agreement is in effect, and for a period of two (2) years after the termination of this Agreement, neither AMNIOLIFE nor TDS, their affiliates, or any directors, shareholders, officers, employees or agents of the foregoing (collectively, the "Affiliates") shall divulge to anyone any Confidential Information (as hereinafter defined) of the other Party, except: (i) as required in the course of performing a Party's obligations hereunder, (ii) to attorneys, accountants and other advisors, (iii) with the express written consent of the disclosing Party or (iv) as required by law provided that the Party to whom the requested Confidential Information belongs be given immediate written notice of any such requirement in order to take steps to prevent or limit such disclosure. The term "Confidential Information" shall mean any information relating to AMNIOLIFE or TDS or their respective businesses which is, (1) disclosed to the other (or to the other's Affiliates) during the negotiation of and performance of this Agreement and (2) marked "Confidential" if provided in writing, or if delivered orally, identified as "Confidential" at the time of oral disclosure; provided, however, the failure to mark a document or information as "Confidential" shall not remove such document or information from being considered "Confidential" or "Confidential Information." "Confidential Information" shall also include the terms and conditions of this Agreement, including its exhibits and schedules, and all intellectual property rights relating to the Donor Tissue. "Confidential Information" shall not include any information which (i) becomes public knowledge without breach by the other Party of this Agreement; (ii) is obtained by the other (or the other's Affiliates) from a person or business entity under circumstances permitting its disclosure to others; (iii) may be demonstrated to have been known at the time of receipt thereof as evidenced by tangible records; or (iv) is required to be disclosed by the AATB for accreditation purposes or as a result of a judicial order or decree or governmental law or regulation provided that the Party to whom the requested Confidential Information belongs be given immediate written notice of any such requirement in order to take steps to prevent or limit such disclosure. Notwithstanding the foregoing, TDS may disclose Confidential Information to debt collectors or accounts receivable collection agencies in order for them or TDS to collect from AMNIOLIFE any unpaid amounts that are payable by AMNIOLIFE to TDS under this Agreement.

- Confidentiality of Protected Health Information. Although TDS and 10.2. AMNIOLIFE are not "covered entities" as defined in federal regulations at 45 C.F.R. Parts 160 and 164 (the "Privacy Standards") promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), TDS may be subject to certain of the Privacy Standards and the security standards at 45 C.F.R. Parts 160 and 164 ("Security Standards") to protect the privacy and security of certain individually identifiable health information ("Protected Health Information" or "PHI"), including electronic protected health information ("EPHI") due to TDS being required by covered entities, such as hospitals, to sign a business associate or other agreement, which requires TDS to obtain written agreement by contractors and subcontractors to be bound by the same restrictions regarding use, confidentiality and nondisclosure of PHI and EPHI as imposed on TDS. AMNIOLIFE agrees (a) to protect the privacy and security of PHI (and EPHI, if applicable) and not to use (or permit the use of) PHI in a manner that would violate the Privacy Standards or Security Standards, (b) to mitigate, to the extent practical any harmful effect that is known to AMNIOLIFE and is the result of a use or disclosure of PHI or EHPI by AMNIOLIFE in violation of the Privacy Standards or the Security Standards following disclosure to AMNIOLIFE of PHI or EHPI by TDS as required by this Agreement. Both TDS and AMNIOLIFE agree to ensure that all disclosures of PHI or EPHI by either Party shall comply with the principle of "minimum necessary use and disclosure" in accordance with 45 C.F.R. §164.502(b) such that only the minimum PHI or EHPI is disclosed that is necessary to accomplish the intended lawful purpose under this Agreement, including compliance with applicable regulatory requirements.
- 10.3. <u>Inspections.</u> **TDS** shall permit, on reasonable notice and not more than three (3) times per year, representatives of **AMNIOLIFE** to inspect all recovery, storage and other facilities of **TDS** and methods of operation used by **TDS** in connection with the recovery and storage of Donor Tissue for the purpose of determining compliance with this Agreement. **AMNIOLIFE's** compliance with audit standards requires a periodic audit of **TDS** and **TDS** tissue recovery facilities.
- 10.4. Notices. Any notices or other communications required or permitted hereunder shall be in writing and shall be sent by (a) personal delivery (including delivery by a reputable overnight courier) or (b) mailed by registered or certified mail, postage prepaid, return receipt requested. Notices shall be sent to the addresses set forth below or to such other addresses as may be hereafter furnished by one Party to the other Party in accordance with the terms hereof. Notices shall be effective upon receipt by the addressee, if sent by personal delivery or mail.

If to AMNIOLIFE:

Gene S Elliott, CTBS, COO AmnioLife Corp. 3542 NW 97<sup>th</sup> Blvd Gainesville, FL 32606

If to TDS:

TDS

- 10.5. <u>Schedules</u>. The Schedules attached hereto are hereby incorporated by reference and made a part of this Agreement. In the event of a conflict between the terms of this Agreement and any Schedule attached hereto, the terms of this Agreement shall govern in all respects.
- 11. <u>Assignment</u>. The rights and obligations of **TDS** or **AMNIOLIFE** hereunder may not be sublicensed, assigned or transferred by operation of law or otherwise without the express written consent of the other Party and consent shall not be unreasonably withheld. Notwithstanding the foregoing, (a) **TDS** may assign this Agreement without consent to an affiliate of **TDS** or any entity to which **TDS** transfers all or substantially all of **TDS**'s tissue services operations; provided that, **TDS** provide prompt written notice to the **AMNIOLIFE** of the transfer, and (b) **TDS** may assign or sell accounts receivable or rights to receive payment from **AMNIOLIFE** to third parties without Client consent.
  - 11.1. <u>Amendment</u>. This Agreement may not be amended except by written document signed by authorized representatives of both parties.
  - 11.2. <u>Headings</u>. Headings used in this Agreement are provided for convenience only and shall not be used to construe meaning or intent.
- 10.9 Entire Agreement. This Agreement, together with the Schedules hereto constitute the entire agreement of the parties hereto with respect to the subject matter hereof and supersede any prior expression of intent or agreement of the parties with respect thereof whether oral or written. This Agreement may be signed in one or more counterparts, each of which will be deemed an original copy and all of which, when taken together, will be deemed to constitute one and the same agreement. Signatures transmitted by facsimile or PDF email scan will be binding to the same extent as an original.
- 10.10 Severability. In the event that any one or more of the provisions contained herein shall, for any reason, be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Agreement, but this Agreement shall be construed as if such invalid, illegal or unenforceable provisions had never been contained herein, unless the deletion of such

- provision or provisions would result in such a material change so as to cause completion of the transactions contemplated herein to be unreasonable.
- 10.11 Waiver. No failure or delay on the part of either Party to enforce any provision of this Agreement or to exercise any right granted hereby shall operate as a waiver thereof unless or until the right to enforce any such provision or to exercise any such right has been waived in writing by such Party. No waiver of any provision hereof or any right hereunder shall constitute a waiver of a continuance or reoccurrence of the failure to perform, except as provided in such waiver.
- 10.12 <u>Independent Contractor</u>. **TDS** and **AMNIOLIFE** are independent organizations and nothing in this Agreement creates the relationship of joint venture, sales agency or principal and agent, and neither Party is the agent of the other, and neither Party may hold itself out as such to any other Party. Each Party shall be free to manage and control its business as it sees fit without the management, control or assistance of the other Party, except as otherwise prescribed herein.
- 10.13 Force Majeure. The parties shall be excused from performing their obligations under this Agreement if performance is delayed or prevented by any event beyond such Party's reasonable control and without the fault or negligence of the Party seeking to excuse performance, including, but not limited to, acts of God, fire, terrorism, explosion, weather, disease, war, insurrection, civil strife, riots, unforeseeable government action, telephone or Internet interruption or power failure, provided, however, such performance shall be excused only to the extent of and during such disability and such Party takes reasonable efforts to remove the disability.
- 10.14 <u>Counterparts</u>. This Agreement may be executed in two or more counterparts, all of which shall be considered one and the same Agreement.
- 10.15 <u>Binding Benefit</u>. The provisions, covenants, and agreements herein contained shall inure to the benefit of, and be binding upon, the Parties hereto and their respective permitted successors and assigns.
- 10.16 No Third Party Beneficiaries. Nothing herein is intended nor shall be construed as creating any rights for any person or entity not a Party hereto, except as expressly stated herein.
- 10.17 <u>Construction</u>. This Agreement shall not be construed more strictly against either Party by virtue of the fact that the Agreement may have been drafted or prepared by such Party or its/his/her counsel, it being recognized that both Parties have contributed substantially and materially to its preparation and that this Agreement has been the subject of and is the product of negotiations between the Parties.

IN WITNESS WHEREOF, the Parties have executed this Tissue Supply Agreement as of the Effective Date first written above.

**AMNIOLIFE:** 

**TEXAS DONOR SERVICES** 

Gene S Elliott, CTBS:

Title: Chief Operating Officer

Print Name: Johnsy Muynk Title: CFO

# **Schedule List**

- $A-Recovery\ Protocol\ for\ AMNIOLIFE$
- **B Donor Acceptance Guidelines**
- **C Donor Recovery Fees**
- **D-TDS Donor Record File (sample)**

## **SCHEDULE A**

# **Recovery Protocol for AMNIOLIFE**

See Work Instructions

# **SCHEDULE B**

# **DONOR ACCEPTANCE CRITERIA**

• See Attachment F-QA-1018 – AmnioLife Donor Acceptance Criteria

### **SCHEDULE C**

#### **Donor Reimbursement Fees**

The fees hereunder represent reimbursement for services provided and both parties agree the fees in this Schedule represent reasonable payments to **TDS** in accordance with NOTA and/or any other applicable regulations and guidelines. The Donor Reimbursement Fees are meant to cover **TDS's** cost of the services provided hereunder and cover the indirect costs of **TDS** recovery which includes but not limited to, personnel, educational efforts, referral screening processes and administrative cost associated with managing the **TDS** operation. Recovery modality is mutually agreed between **TDS** and **AMNIOLIFE**.

### Recovery modalities include but not limited to:

- a) Leg-en-bloc consisting of whole femur, tibia, fibula and talo-calcaneal block with all musculature and soft tissues from distal half of the femur to talo-calcaneal block attached as a single unit,
- b) Lower leg-en-bloc consisting of whole tibia, fibula and talo-calcaneal block with all musculature and soft tissues attached as a single unit, (quad and patella rolled down to Tibia.)
- c) Intercalary/disarticulated as individual tissues consisting of single whole tissue units as described below.

Donor	M 18-55/F-15-45	M 56-70/F 56-65	M 71-85	REJECT
				FEE
Male	\$11,000	\$8,000	\$6,000	\$3,000
Female	\$8,500	\$4,000		\$3,000
PLACENTA/AMNION	\$1100			
AMNIOTIC FLUID	\$1000 (>300cc's)			

### Gestational Recovery

- d) Placenta / Amnion either the entire placenta with amnion attached or the amnion completely disarticulated from them Amnion.
- e) Amniotic Fluid recovered sterile with little or no red blood cells and in an amount greater that 300cc's.

### SCHEDULE D

### TDS DONOR RECORD FILE

# Current donor file revisions will be included upon delivery of this contract to AMNIOLIFE.

- Consent Documentation
- Tissue Recovery info Sheet
- Plasma/Hemo Dilution Worksheet (all MS AND Gestational Donors)
- Medical Records
- ALS/EMS Info
- Autopsy/Coroner/ME Final Report
- Physical Assessment
- Facility Cleaning information (Place of MS Tissue Recovery)
- Any additional information pertinent to recovery not listed herein